MAR 15 2005

K050206

Section II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

510(k) Number:

Submitter:

Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538
Telephone: (510)-979-5142
Facsimile: (510) 979-5455

Contact Person:

Lisa Charter
Research and Development Supervisor
Telephone: (510)-979-5142
Facsimile: (510) 979-5455

Alternate Contact:
Candice Betz
Manager of Regulatory and Quality Affairs
Telephone: (510)-979-5169

Preparation Date:

January 27, 2005

Device Information:

Proprietary Name:	CEDIA® Tacrolimus Assay
Device Description:	Enzyme Immunoassay, Tacrolimus
Product Code:	MLM
Regulation Number:	21 CFR§862.1678.
Regulatory Class:	Class 2 (special controls)

Predicate Device(s):

The data and results described herein demonstrate that the CEDIA® Tacrolimus Assay is substantially equivalent to IMx® Tacrolimus II (MEIA) for the quantitative determination of tacrolimus (FK506) concentration in human whole blood as an aid in the management of kidney and liver transplant patients receiving therapy with tacrolimus.

Device Description:

The CEDIA® Tacrolimus Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments i.e., enzyme acceptor (EA) and enzyme donor (ED). These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment (ED) of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of analyte present in the sample.

Intended Use:

The CEDIA® Tacrolimus Assay is an in vitro diagnostic medical device intended for the quantitative determination of tacrolimus in human whole blood using automated clinical chemistry analyzers as an aid in the management of kidney and liver transplant recipients receiving tacrolimus therapy.

CEDIA® Tacrolimus Calibrators are intended for calibration of the CEDIA® Tacrolimus Assay in whole blood.

Comparison to Predicate Device(s):

The CEDIA® Tacrolimus Assay is substantially equivalent to IMx® Tacrolimus II (MEIA) in its intended use and in for the quantitative determination of tacrolimus (FK-506) concentration as an aid in the management of kidney and liver transplant patients receiving therapy with tacrolimus.

Device Characteristics	Subject Device (CEDIA® Tacrolimus Assay)	Predicate Device Abbott Laboratories IMx® Tacrolimus II (MEIA)
Intended Use	The CEDIA® Tacrolimus Assay is an in vitro diagnostic medical device intended for the quantitative determination of tacrolimus in human whole blood using automated clinical chemistry analyzers as an aid in the management of kidney and liver transplant recipients receiving tacrolimus therapy. CEDIA® Tacrolimus Calibrators are intended for calibration of the CEDIA® Tacrolimus Assay in whole blood.	The IMx® Tacrolimus II assay is an in vitro reagent system for the quantitative determination of tacrolimus and some metabolites in human whole blood and as an aid in the management of liver allograft patients receiving tacrolimus therapy. The IMx® Tacrolimus II Calibrators are for calibration of the IMx® analyzer when used for the quantitative determination of tacrolimus in human whole blood.
Analyte	Tacrolimus	Tacrolimus
Matrix	Whole blood extract	Whole blood extract
Calibrator Form	Liquid	Liquid
Calibrator Level	Two (2) Levels (0 and 30 ng/mL)	Six (6) Levels (0, 3, 6, 12, 20, and 30 ng/mL)
Storage	Reagents are stored at 2°C to 8°C until expiration date. Calibrators are stored at -20°C until expiration date.	Reagents are stored at 2°C to 8°C until expiration date. Calibrators are stored frozen until expiration date.
Stability	Until expiration date noted on vial label and Package Insert.	Until expiration date noted on vial label.

Summary:

The information provided in this pre-market notification demonstrates that the CEDIA® Tacrolimus Assay is substantially equivalent to the IMx® Tacrolimus II assay. The IMx® Tacrolimus II assay is commonly used for determination of tacrolimus concentration in whole blood samples obtained from patients receiving tacrolimus for post-operative management following hepatic transplant. Data and results provided in this premarket notification were collected and prepared, respectively, in accordance with the established guideline, "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA", dated September 16, 2002. , These data and results amply demonstrate that the CEDIA® Tacrolimus Assay is substantially equivalent to the IMx® Tacrolimus II assay for the quantitative determination of tacrolimus (FK506) in human whole blood using automated clinical chemistry analyzers as an aid in the management of kidney and liver transplant patients receiving therapy with tacrolimus.

CEDIA® is a registered trademark of Roche Diagnostics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 15 2005

Ms. Lisa Charter
Research and Development
Microgenics Corp.
46360 Fremont Blvd
Fremont, CA 94538

Re: k050206
Trade/Device Name: CEDIA® Tacrolimus Assay
CEDIA® Tacrolimus Calibrators
Regulation Number: 21 CFR 862.1678
Regulation Name: Tacrolimus test system
Regulatory Class: Class II
Product Code: MLM, JIT
Dated: January 27, 2005
Received: January 28, 2005

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SECTION III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K050206

Device name: CEDIA® Tacrolimus Assay
CEDIA® Tacrolimus Calibrators

Indications for Use:

The CEDIA® Tacrolimus Assay is an in vitro diagnostic device intended for use with automated clinical chemistry analyzers for the quantitative determination of tacrolimus in human whole blood as an aid in the management of kidney and liver transplant recipients receiving tacrolimus therapy.

CEDIA® Tacrolimus Calibrators are intended for calibration of the CEDIA® Tacrolimus Assay in whole blood.

Prescription Use __X_____ AND/OR Over-the Counter Use_____
(Part 21 CFR §801 Subpart D) (21 CFR §807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

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...d Safety

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